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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,859	03/19/2004	John Mattick	DAVI199.005CP1	7975

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EXAMINER

DEJONG, ERIC S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/804,859

Applicant(s)

MATTICK ET AL.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☒ Claim(s) 1-3 and 5-61 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED OFFICE ACTION

### *Claim Objections*

Claim 4 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 4 not been further treated on the merits.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 5-48, and 61, drawn to a method for identifying an eRNA or DNA sequence, a receiver DNA or RNA sequence, or a receiver protein and a method for detecting an altered genetic network comprising screening for the presence or absence of an eRNA, classified in class 702, subclass 19. If this Group is elected then the two Species Elections summarized below are also required.
- II. Claims 49-52, drawn to a computer program product and computer system for assessing the likelihood of a candidate sequence or group of sequences being an eRNA or a receiver for an eRNA involved in network genetic signaling, classified in class 703, subclass 11.
- III. Claim 53, drawn to an eRNA molecule, classified in class 536, subclass 23.1.
- IV. Claim 54, drawn to a receiver DNA or RNA molecule, classified in class 536, subclass 23.1.

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- V. Claim 55, drawn to a receiver protein, classified in class 530, subclass 350.
- VI. Claim 56-60, drawn to a method of inducing post transcriptional gene silencing in a eukaryotic cell, classified in class 435, subclass 6. If this Group is elected then the Species Election summarized below is also required.

The inventions are distinct, each from the other because of the following reasons:

The inventions Groups I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In the instant case, the process as claimed in Group I can be practiced by hand.

The inventions of Groups I and II and Groups III-V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the nucleic acid and protein products of Groups III-V can be made by synthetic or combinatorial techniques.

The inventions of Groups III-V are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the eRNA of Group III and the receiver DNA or RNA of Group IV have materially different modes of operation, functions and effects. Further, the receiver protein of Group V has a materially design that the nucleic acids of either Groups III and IV. The specific biopolymer sequences for the eRNA of Group III, the receiver DNA or RNA of group IV, and the receiver protein of Group V are distinct each from the other and demonstrates that the inventions do not overlap in scope. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The inventions of Groups III-V and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products of Groups III-V may be used in materially different processes as identified by either of Groups I and II.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

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because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***First Required Species Election for Group I***

This application contains claims directed to the following patentably distinct species:

Species of where an eRNA is derived from as set forth in claims 6, 7, 23, 24, 36, and 37 represent distinct genomic locations. The distinct genomic locations are separately described in literature thus presenting an undue burden of search of searched together. Applicants are to elect one of the following disclosed species (A or B) of where an eRNA is derived from:

Species A (claims 6, 23, 36): wherein the eRNA is derived from an intron, or

Species B (claims 7, 24, 37): wherein the eRNA is derived from an exon.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-3, 5, 8-22, 25-35, and 38-48 are generic.

***Second Required Species Election for Group I***

This application contains claims directed to the following patentably distinct species:

Species of eukaryotic cells as set forth in claims 9-18, 25-34, and 39-48 each represent distinct eukaryotic cell systems. The distinct eukaryotic cell systems are each

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separately described in literature thus presenting an undue burden of search of searched together. Applicants are to elect one of the following disclosed species (C-E) of where an eRNA is derived from:

Species C (claims 9, 11-15, 25, 27-31, 39, and 41-45): wherein the eukaryotic cell is from a vertebrate. If Species C is elected then the Sub-species election requirement summarized below is also required

Species D (claims 10, 26, and 40): wherein the eukaryotic cell is from an invertebrate.

Species E (claims 16-18, 32-34, and 46-48): wherein the eukaryotic cell is from a plant. If Species E is elected then the Sub-Species Election requirement summarized below is also required.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 5-8, 19-24, 35-38, and 61 are generic.

***Required Sub-Species Election for Species C***

This application contains claims directed to the following patentably distinct sub-species:

Species of vertebrates as set forth in claims 11-15, 27-31 and 41-45 represent distinct vertebrates. The distinct vertebrates are separately described in literature thus



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presenting an undue burden of search of searched together. Applicants are to elect one of the following disclosed species (C1-C4) of vertebrates:

Species C1 (claims 11, 15, 27, 31, 41, and 45): wherein the vertebrate is a mammal.

Species C2 (claims 12, 28, and 42): wherein the vertebrate is an avian species.

Species C3 (claims 13, 29, and 43): wherein the vertebrate is a reptilian species.

Species C4 (claims 14, 30, and 44): wherein the vertebrate is an amphibian species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 9, 25, and 39 are generic.

#### ***Required Sub-Species Election for Species E***

This application contains claims directed to the following patentably distinct sub-species:

Species of plants as set forth in claims 17, 18, 33, 34, 47, and 48 represent distinct plants. The distinct plants are separately described in literature thus presenting an undue burden of search of searched together. Applicants are to elect one of the following disclosed species (E1 or E2) of plants:

Species E1 (claims 17, 33, and 47): wherein the plant is a monocotyledonous plant.

Species E2 (claims 18, 34, and 48): wherein the plant is a dicotyledonous plant.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 16, 32, and 46 are generic.

***Required Species Election for Group VI***

This application contains claims directed to the following patentably distinct species:

Species of cells as set forth in claims 57-59 each represent distinct eukaryotic cell systems. The distinct eukaryotic cell systems are each separately described in literature thus presenting an undue burden of search of searched together. Applicants are to elect one of the following disclosed species (F or G) of where an eRNA is derived from:

Species F (claims 57): wherein the cell is a plant cell.

Species G (claims 58 and 59): wherein the cell is a mammalian cell.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 56 and 60 are generic.

Applicant is advised that a reply to the above species election requirements must include an identification of the species that are elected consonant with these requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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*John S. Brusca 29 September 2006*  
JOHN S. BRUSCA, PH.D  
PRIMARY EXAMINER